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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 02-479-E

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on _____

Signature _____

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Application Number	Filed
10766403	1/27/04

First Named Inventor: Belardinelli et al.

Art Unit	Examiner
1623	Crane

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 32901.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

/A. Blair Hughes/
Signature

A. Blair Hughes
Typed or printed name

312-913-2123
Telephone number

October 1, 2009
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(02-479-E)

In Re Application of:
Belardinelli, et al.

Confirmation No.: 3369

Serial No.: 10/766,403

Group Art Unit: 1623

Filing Date: January 27, 2004

Examiner: Lawrence E. Crane

Title: Myocardial Perfusion Imaging Method

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF

Sir:

Claims 74, 77 and 79-89 are pending in the application. All claims stand rejected for double-patenting and for including claims that conflict with other pending applications. Both rejections are traversed below.

I. ALL DOUBLE PATENTING REJECTIONS ARE LEGALLY FLAWED

The examiner rejected all application claims for double patenting or for provisional double patenting over a total of eight (8) commonly owned U.S. patents and patent applications. The double patenting rejections must be withdrawn because they are not based upon a legally proper analysis of the claims of the cited offending patents or applications in combination with the teachings of the prior art.

A. A Proper Double Patent Analysis

An obviousness type double patenting analysis requires the comparison of one or more claims of an applicant's earlier patent or patent application with one or more pending application claims to determine if applicant's other patent or application claim(s) along with any cited prior art renders the pending application claims obvious. The specification of the cited commonly owned patents or patent applications may not be used in an obviousness type double patenting rejection as prior art. Instead, the examiner may only resort to the specifications of the commonly owned patents and application in order to understand the meaning of terms of any claims cited in the double patenting rejection.

MPEP §804(II)(B)(1) summarizes the factual inquiries that must be made in an obviousness-type double patenting analysis. The inquiries are:

(A) Determine the scope and content of a patent claim relative to a claim in the application at issue;

(B) Determine the differences between the scope and content of the patent claim as determined in (A) and the claim of the application at issue;

(C) Determine the level of ordinary skill in the pertinent art; and

(D) Evaluate any objective indicia of nonobviousness.

Id. (emphasis added). Thus the proper double patenting analysis requires a comparison of the claim(s) of a patent application with claims of another patent or patent application owned by the same Applicant.

B. The Examiner Has Improperly Based The Double Patent Rejections On What The Conflicting Specifications Teach An Not What They Claim

The examiner's obviousness-type double patent rejections are flawed because they each compare – not what is claimed – but what is taught in the specification of an allegedly conflicting patent or patent application with what is being claimed in the current application. For example, the examiner's analysis of Applicant's co-pending application 10/629,368 for double patenting is reproduced below.

> Claims **74, 77 and 79-89** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims *1-11* of copending Application No. **11/253,322** in view of **Swinyard et al. (II)** (PTO-892 ref. **S**) and further in view of **Harvey** (PTO-892 ref. **T**).
>
> In the portion of the **'322** application at pages 8-9, the pharmaceutical compositions comprising CVT-3146 are defined with carriers including "buffers." This application is also directed to the administration of the buffered CVT-3146 compositions to induce a brief vasodilation of cardiac vasculature for the purpose of permitting concomitant contrast agent administration and simultaneous visualization of possible blockages therein.
>
> The **'322** reference does not specify or otherwise teach buffered compositions comprising CVT-3164 with a pH in the range of pH 8.5 and 10.

The **Swinyard et al. (II)** reference (PTO-892 ref. **S**) is a very well known in the art source of guidance concerning how to prepare a pharmaceutical composition. In this Chapter of Remington's Pharmaceutical Sciences applicant will find the pharmaceutical excipients EDTA (p. 1321, col. 2), various grades of water (pages 1300-1301 et seq), and propylene glycol (page 1317). In addition in **Harvey et al.** (PTO-892 ref. **T**) applicant will find at page 821 the buffer sodium phosphate and a brief description of how to prepare buffers therefrom.

In light of the generic teaching of "buffered" CVT-3146 compositions in the **'322** application and the teachjings of **Swinyard et al. (II)**, development of the specific examples at page 37 herein would have been obvious variations of the buffers taught generically by the **'322** application in order to obtain a pH 6-to-pH 8 buffered composition comprising CVT-3146.

Notably, there is absolutely no comparison of the scope and content of the claims of the present application or the scope and content of the '322 application claims and there is no attempt to indentify differences between the claims as the double patenting test requires. This same analysis defect is present in all of the examiner's double patenting rejections. For this reason, every obviousness-type double patenting rejection must with withdrawn.

C. There Is No Double Patenting

Following a proper analysis, the examiner must conclude that there is no double patenting. The present application includes claims directed to a pharmaceutical composition and methods for its administration where the composition includes the compound CVT-3146 and certain specific pharmaceutical excipients. The claimed pharmaceutical excipients are (1) sodium phosphate; (2) propylene glycol; and (3) EDTA.

1. The '322 Application Claims

The examiner rejected claims 74, 77 and 79-89 for obviousness-type double patenting in view of claims 1-11 of Applicant's co-pending application no. 11/253,322. Claim 1 of the '322 application is directed generally to a method of producing coronary vasodilatation with little peripheral vasodilatation comprising administering to a human a single intravenous (iv) bolus dose of a pharmaceutical composition comprising regadenoson (CVT-3146) and at least one pharmaceutical excipient. No specific excipients are claimed. The examiner is reminded that the specification may be consulted to construe the term "excipient" but it cannot be construed to read certain excipients – such as buffers – into the claims. As a result, one dramatic difference

between the pending claims and the claims of the '322 application is the claiming of a specific pharmaceutical excipients in the present application.

To establish *prima facie* obviousness, two basic criteria must be met. First, there must be some suggestion or motivation to combine the teachings of different references – in this case, Applicant's co-owned patent and application claims with Swinyard et al. Second, there must be a reasonable likelihood of success in light of the prior art. *Brown & Williamson Tobacco Corp. v. Phillip Morris Inc.* 229 F.3d 1120, 56 USPQ2d 1456, 1459 (2000) citing *In re Dow Chem.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). The claimed compositions, which include specific excipients in a pharmaceutical composition including CVT-3146 are not obvious. There are literally thousands of pharmaceutical excipients that may be used in pharmaceutical composition formulations. Indeed, the Swinyard reference must disclose hundreds of possible excipients. The evaluation of each possible Swinyard excipients for efficacy with CVT-3146 would be a daunting task that would require undue experimentation. Indeed, the preparation of a pharmaceutical formulation is often a trial and error process and the choice of excipients is not necessarily obvious or readily apparent based upon the pharmaceutically active composition itself nor upon the desired administration method. The Swinyard reference discloses a plethora of pharmaceutical excipients. The selection of the three claimed excipients from the vast number disclosed in Swinyard in view of the claims of the '322 application would clearly not be obvious to one skilled in the art at the time of the invention without undue experimentation. As a result the all pending application claims are patentable over the claims of the '322 application.

2. The Remaining Conflicting Claims

All pending application claims are non-obvious over claims of the remaining allegedly conflicting patents and applications for at least the same reasons recited in Section I(C)(1) above. In particular:

- The double patenting rejections with respect to application no. 10/629,368 and patent no. 7,144,872 cannot be sustained because all '368 application and '872 patent claims only disclose CVT-3146 - no pharmaceutical excipients are claimed.
- The double patenting rejection with respect to application no. 11/070,768 cannot be sustained because the '768 application claims disclose only CVT-3146 and CVT-3033

and that the compounds be formulated into a liquid. The claims are silent about including pharmaceutical excipients.

- The double patenting rejection with respect to U.S. patent nos. 7,183,264, 6,642,210, 6,403,567 and application no. 11/588,834 cannot be sustained. At least one claim of each patent or application is directed to a pharmaceutical composition that includes "at least one pharmaceutical excipient". However, none of the patent or application claims identifies any specific excipients nor do the claims suggest any useful excipients. The present application claims are, therefore, not obvious over claims of the patents and applications listed above in combination with Swinyard for at least the same reasons recited in section I(C)(1) above.

II. THE ALLEGED CONFLICTING CLAIMS

The examiner has taken the position that claims 74, 77 and 79-89 of this application conflict under 37 CFR §1.78(b) with claims of co-pending patent application nos. 10/629,368; 11/070,768; 11/253,322; and 11/588,834. The examiner goes on to require the Applicant to cancel the conflicting claims or to maintain a clear line of demarcation between the applications.

The examiner's rejection must be withdrawn because no claim of the present application is identical to any claim of the recited applications. Moreover, all of the claims of the different applications are patentably distinct from one another. For at least these reasons, the examiner's position that the applications include "conflicting claims" is traversed.

Respectfully submitted,

McDonnell Boehnen Hulbert & Berghoff

Date: October 1, 2009

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